IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P. and NAPP PHARMACEUTICAL GROUP LTD., Plaintiffs/Counterclaim-Defendants, -v- LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants/Counterclaim-Plaintiffs.	C.A. No. 10-049 (KAJ)

ANSWER, AFFIRMATIVE AND SEPARATE DEFENSES AND COUNTERCLAIMS OF DEFENDANTS LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.

Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by Plaintiffs Purdue Pharma Products, L.P., and Napp Pharmaceutical Group, Ltd. (collectively, "Purdue"), as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

ANSWER: Lupin admits that this action arises under the patent laws of the United States, Title 35, United States Code, and that the Complaint includes an allegation of patent infringement.

THE PARTIES

2. Plaintiff Purdue Pharma Products L.P. ("Purdue") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One

Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue is an owner by assignment of the patents-in-suit identified in paragraph 11 below.

ANSWER: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and, therefore, denies them.

3. Plaintiff Napp Pharmaceutical Group Ltd. ("Napp") is a private limited company organized and existing under the laws of the United Kingdom, having a place of business at Cambridge Science Park, Milton Road, Cambridge, CB4 OGW. Napp is an owner by assignment of the patents-in-suit identified in paragraph 11 below.

ANSWER: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Complaint and, therefore, denies them.

4. Upon information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai, 400 051, India.

ANSWER: Lupin Limited admits that it is a corporation organized and existing under the laws of India, and has a place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai, 400 051, India. Lupin denies the remaining allegations in paragraph 4 of the Complaint.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. ("LPI"), a wholly-owned subsidiary and agent of Lupin Ltd., is a Virginia corporation having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, LPI markets, sells, and distributes products for Lupin Ltd. in the United States, including this Judicial District.

ANSWER: Lupin Pharmaceuticals, Inc., admits that it is a corporation organized and existing under the laws of the Commonwealth of Virginia, and has a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals, Inc., further admits that it is a wholly-owned subsidiary of Lupin Limited. Lupin denies the remaining allegations in paragraph 5 of the Complaint.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

ANSWER: Admitted.

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has purposefully availed itself of the rights and benefits of Delaware law, regularly does and solicits business in Delaware, has engaged in continuous and systematic contact with the State of Delaware, and derives substantial revenue from things used or consumed in the State of Delaware. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Lupin does not contest personal jurisdiction in this judicial district for purposes of the present action only. Lupin denies the remaining allegations in paragraph 7.

8. This Court has personal jurisdiction over Defendant Lupin Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Among other things, upon information and belief, Lupin Ltd., directly or through its wholly-owned subsidiary and agent LPI, purposefully sells, markets, distributes, and manufactures goods for sale in the United States and the State of Delaware, derives substantial revenue from things used or consumed in the State of Delaware, regularly does and solicits business in the State of Delaware, has purposefully availed itself of this forum by filing counterclaims in this Court, and has admitted and/or consented to jurisdiction in this Court on numerous occasions.

ANSWER: Lupin Limited does not contest personal jurisdiction in this judicial district for purposes of the present action only. Lupin denies the remaining allegations in paragraph 8.

9. This Court has personal jurisdiction over Defendant LPI by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Among other things, upon information and belief, LPI, directly or though its parent company Lupin Ltd., purposefully sells, markets, and distributes goods for sale in the United States and the State of Delaware and derives substantial revenue from things used or consumed in the State of Delaware, is registered to do business in and regularly does and solicits business in the State of Delaware, has purposefully availed itself of this forum by filing counterclaims in this Court, and has admitted and/or consented to jurisdiction in this Court on numerous occasions.

ANSWER: Lupin Pharmaceuticals, Inc., does not contest personal jurisdiction in this judicial district for purposes of the present action only. Lupin denies the remaining allegations in paragraph 9.

10. Venue is proper in this Judicial District under 28 U.S.C. § 1391 and § 1400(b).

ANSWER: Lupin does not contest venue in this judicial district for purposes of the present action only. Lupin denies the remaining allegations of paragraph 10.

THE PATENTS-IN-SUIT

11. Purdue and Napp are the lawful owners of all right, title and interest in and to the following two United States patents, including all right to sue and to recover for past infringement thereof:

(a) United States Patent No. 6,254,887, entitled "CONTROLLED RELEASE TRAMADOL" ("the '887 patent"), a copy of which is attached hereto as Exhibit A, which was duly and legally issued on July 3, 2001, naming Ronald Brown Miller, Stewart Thomas Leslie, Sandra Therese Antoinette Malkowska, Kevin John Smith, Walter Wimmer, Horst Winkler, Udo Hahn and Derek Allan Prater as the inventors. The '887 patent is among the patents listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering Ultram® ER, a controlled-release tramadol hydrochloride pain relief medication.

(b) United States Patent No. 7,074,430, entitled "CONTROLLED RELEASE TRAMADOL TRAMADOL [sic] FORMULATION" ("the '430 patent"), a copy of which is attached hereto as Exhibit B, which was duly and legally issued on July 11, 2006, naming Ronald Brown Miller, Sandra Therese Antoinette Malkowska, Walter Wimmer, Udo Hahn, Stewart Thomas Leslie, Kevin John Smith, Horst Winkler and Derek Allan Prater as the inventors. The '430 patent is among the patents listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering Ultram® ER, a controlled-release tramadol hydrochloride pain relief medication.

ANSWER: Lupin admits that U.S. Patent No. 6,254,887 is entitled "CONTROLLED RELEASE TRAMADOL" ("the '887 patent"), and what purports to be a copy of the '887 patent is attached to the Complaint as Exhibit A. Lupin further admits that the issue date set forth on the face of the '887 patent is July 3, 2001, and that paragraph 11(a) of the

Complaint accurately recites the names of the individuals identified as inventors on the face of the '887 patent. Lupin further admits that the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the *Orange Book*") lists the '887 patent in connection with Ultram® ER.

Lupin admits that U.S. Patent No. 7,074,430 is entitled "CONTROLLED RELEASE TRAMADOL TRAMADOL [sic] FORMULATION" ("the '430 patent"), and what purports to be a copy of the '430 patent is attached to the Complaint as Exhibit B. Lupin further admits that the issue date set forth on the face of the '430 patent is July 11, 2006, and that paragraph 11(b) of the Complaint accurately recites the names of the individuals identified as inventors on the face of the '430 patent. Lupin further admits that the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the *Orange Book*") lists the '430 patent in connection with Ultram® ER.

Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 11 of the Complaint and, therefore, denies them.

ANDA NO. 200503

12. Upon information and belief, Lupin Ltd. and LPI (collectively "Lupin") submitted Abbreviated New Drug Application No. 200503 ("ANDA") to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use or sale of tramadol hydrochloride controlled-release tablets, 100 mg, 200 mg, and 300 mg ("the Lupin Tablets"), a generic version of Ultram® ER, before the expiration of the '887 and '430 patents.

ANSWER: Lupin Limited admits that it submitted Abbreviated New Drug Application No. 200503 (Lupin Limited's "ANDA") to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the manufacture, use or sale of tramadol hydrochloride extended-

release tablets, 100 mg, 200 mg, and 300 mg. Lupin denies the remaining allegations in paragraph 12.

13. Upon information and belief, Lupin Ltd. and LPI are in the same corporate family and share directors and officers, and Lupin Ltd. and LPI were and continue to be actively involved in the preparation of ANDA No. 200503.

ANSWER: Lupin admits that Lupin Pharmaceuticals, Inc., is a wholly-owned subsidiary of Lupin Limited, and that Lupin Limited submitted ANDA No. 200503 to the FDA. Lupin denies the remaining allegations of paragraph 13.

14. Upon information and belief, Lupin Ltd. and LPI will be involved in the manufacturing, marketing, selling and/or distribution of the Lupin Tablets if ANDA No. 200503 is approved by the FDA.

ANSWER: Lupin Limited admits that it submitted Abbreviated New Drug Application No. 200503 (Lupin Limited's "ANDA") to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the manufacture, use or sale of tramadol hydrochloride extended-release tablets, 100 mg, 200 mg, and 300 mg. Lupin denies the remaining allegations in paragraph 14.

15. Upon information belief, Lupin Ltd. has specifically named LPI as its agent for ANDA No. 200503.

ANSWER: Lupin Limited admits that it named Lupin Pharmaceuticals, Inc., as an authorized United States agent for ANDA No. 200503. Lupin denies the remaining allegations of paragraph 15.

16. Upon information and belief, Lupin's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '887 and '430 patents, listed in the FDA's Orange Book as two of the patents covering Ultram® ER, "are invalid and/or will not be infringed by Lupin's tramadol tablets."

ANSWER: Lupin Limited admits that its ANDA No. 200503 contains "Paragraph IV" certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certifying that in the opinion of Lupin Limited, and to the best of Lupin Limited's knowledge, the '430 and '887 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the tramadol tablets (100 mg, 200 mg, and 300 mg) that are the subject of ANDA No. 200503. Lupin denies the remaining allegations of paragraph 16.

17. In a letter dated December 8, 2009 addressed to Purdue, Napp, Biovail Labs International SRL, Biovail Laboratories International SRL, Biovail Corporation, and Davidson, Davidson & Kappel, LLC, Lupin provided "notice" with respect to the Lupin Tablets and the '887 and '430 patents under 21 U.S.C. § 355(j)(2)(B)(ii) ("Lupin's Notice Letter").

ANSWER: Lupin admits that a letter dated December 8, 2009, addressed to Purdue Pharma Products L.P., Napp Pharmaceutical Group, Ltd., Davidson, Davidson & Kappel, LLC, Biovail Labs International SRL, Biovail Laboratories International SRL, and Biovail Corporation, states that Lupin Limited filed ANDA No. 200503 with the FDA seeking approval to manufacture, use, or sell the tramadol tablets that are the subject of ANDA No. 200503 in the United States, and that said letter constituted proper notice under 21 U.S.C. § 355(j)(2)(B)(ii). Lupin denies the remaining allegations of paragraph 17.

PATENT INFRINGEMENT OF THE '887 & '430 PATENTS

18. Lupin's submission of its ANDA was an act of infringement of the '887 and '430 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

ANSWER: As paragraph 18 of the Complaint sets forth a legal conclusion or argument, no response is required. To the extent paragraph 18 of the Complaint is construed as containing any factual allegations, Lupin denies them.

19. Upon information and belief, the Lupin Tablets are covered by one or more claims of the '887 and '430 patents.

ANSWER: As paragraph 19 of the Complaint sets forth a legal conclusion or argument, no response is required. To the extent paragraph 19 of the Complaint is construed as containing any factual allegations, Lupin denies them.

20. Upon information and belief, Lupin's commercial manufacture, use, sale, and/or offer for sale of the Lupin Tablets would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '887 and '430 patents.

ANSWER: As paragraph 20 of the Complaint sets forth a legal conclusion or argument, no response is required. To the extent paragraph 20 of the Complaint is construed as containing any factual allegations, Lupin denies them.

21. Upon information and belief, Lupin has been aware of the existence of the '887 and '430 patents and has no reasonable basis for believing that the Lupin Tablets will not infringe the '887 and '430 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

ANSWER: As paragraph 21 of the Complaint sets forth a legal conclusion or argument, no response is required. To the extent paragraph 21 of the Complaint is construed as containing any factual allegations, Lupin denies them.

22. The acts of infringement by Lupin set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

ANSWER: As paragraph 22 of the Complaint sets forth a legal conclusion or argument, no response is required. To the extent paragraph 22 of the Complaint is construed as containing any factual allegations, Lupin denies them.

***PURDUE V. PAR* CASE**

23. On May 5, 2007, Plaintiffs Purdue and Napp along with Ortho-McNeil, Inc. ("Ortho") and Biovail Laboratories International, SRL ("Biovail"), filed suit against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") in the District of Delaware, C.A. No. 07-255-KAJ, alleging infringement of the '887 patent ("the *Par* case"). On March 28, 2008, Plaintiffs Purdue and Napp along with Ortho and Biovail, filed an amended

complaint against Par additionally seeking declaratory judgment of patent infringement of the '430 patent. In response, Par denied infringement and asserted that the claims of the patents-in-suit were invalid and unenforceable due to inequitable conduct. Biovail was dismissed by consent on November 10, 2008. Ortho was dismissed for lack of standing on December 3, 2008. A five-day bench trial was held from April 16 to April 22, 2009.

ANSWER: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint and, therefore, denies them.

24. On August 14, 2009, the District Court in *Par* issued a Judgment Order and Findings of Fact and Conclusions of Law on the asserted claims of the '887 and '430 patents that were at issue in the *Par* case. The Court found and adjudged, inter alia, that:

(a) Par has literally infringed asserted claims 3, 13, 27, and 29 of the '887 patent, and Par's manufacture, use, and offer to sell tramadol controlled-release tablets in 100 mg, 200 mg, and 300 mg dosage strengths would infringe asserted claims 5, 7, and 11 of the '430 patent;

(b) Asserted claims 3, 13, 27, and 29 of the '887 patent and asserted claims 5, 7, and 11 of the '430 patent are invalid for obviousness; and

(c) The '887 patent and '430 patents are not unenforceable due to inequitable conduct.

ANSWER: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 of the Complaint and, therefore, denies them.

25. On September 3, 2009, Plaintiffs Purdue and Napp filed a Notice of Appeal appealing the District Court's judgment of invalidity in the *Par* case to the U.S. Court of Appeals for the Federal Circuit. That appeal is currently pending.

ANSWER: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 of the Complaint and, therefore, denies them.

THE FILING OF THIS SUIT

26. Under the Hatch-Waxman Act, Plaintiffs have 45 days after receipt of Lupin's Notice Letter to sue for infringement of the '887 and '430 patents to trigger a 30-month stay during which the FDA cannot approve Lupin's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). There can be no such stay while the patents remain invalid. The law is unclear as to whether, following a successful appeal of the District Court's decision in the *Par* case, Plaintiffs would have a right to a statutory stay of FDA approval of Lupin's ANDA if they were to file suit at that time. However, there appears to be no mechanism in the Hatch-Waxman Act by which Plaintiffs can

toll the statutory requirement that suit be filed within 45 days of receipt of Lupin's Notice Letter in order for Plaintiffs to obtain such a stay, or to revive Plaintiffs' right to such a stay, if suit is not filed within 45 days.

ANSWER: As paragraph 26 of the Complaint sets forth legal conclusions or arguments, no response is required. To the extent paragraph 26 of the Complaint is construed as containing any factual allegations, Lupin denies them.

27. Accordingly, Plaintiffs must file suit against Lupin for the infringement of the Lupin Tablets within the 45-day timeframe provided by statute, in order to perfect their rights to a statutory stay prohibiting FDA approval of Lupin's ANDA if the Federal Circuit vacates or reverses the District Court's judgment in Par.

ANSWER: As paragraph 27 of the Complaint sets forth legal conclusions or arguments, no response is required. To the extent paragraph 27 of the Complaint is construed as containing any factual allegations, Lupin denies them.

28. Since initiating the *Par* case, seven other pharmaceutical companies, including Lupin, have provided "notice" to Plaintiffs of "Paragraph IV" certifications relating to seeking FDA approval of controlled-release tramadol products. In the interest of efficiency, Plaintiffs have moved the Judicial Panel on Multidistrict Litigation ("MDL Panel") to centralize five previously-filed actions in this Court. (*In re: Tramadol Hydrochloride Extended-Release Tablets Patent Litigation*, MDL No. 2126). That motion is pending.

ANSWER: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28 of the Complaint and, therefore, denies them.

29. Plaintiffs intend to notify the MDL Panel about this action as a tag-along action to be included in that multidistrict litigation. If and when Plaintiffs commence suit against the remaining two companies who have provided Paragraph IV notices, Plaintiffs will seek to have those actions included in the multidistrict litigation proceeding as well.

ANSWER: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the Complaint and, therefore, denies them.

30. To conserve the resources of the Court and the parties, Plaintiffs will move promptly for a stay of this action against Lupin until (a) Plaintiffs' motion requesting that the MDL Panel centralize this action with the other controlled-release tramadol cases is resolved;

and (b) the earlier of (i) a final adjudication of the appeal in the *Par* case or (ii) a decision by the FDA to tentatively approve the Lupin Tablets.

ANSWER: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30 of the Complaint and, therefore, denies them.

PRAYER FOR JUDGMENT

A. Adjudging that Lupin has infringed the '887 and '430 patents, and that the commercial sale, offer for sale, and/or manufacture of the Lupin Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '887 and '430 patents;

ANSWER: Lupin denies that plaintiffs are entitled to the judgment and relief requested in paragraph A of the Prayer for Judgment set forth in the Complaint.

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin's ANDA No. 200503, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '887 and '430 patents plus any additional periods of exclusivity;

ANSWER: Lupin denies that plaintiffs are entitled to the judgment and relief requested in paragraph B of the Prayer for Judgment set forth in the Complaint.

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, FED. R. CIV. P., Lupin, its partners, contractors, officers, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '887 or '430 patents;

ANSWER: Lupin denies that plaintiffs are entitled to the judgment and relief requested in paragraph C of the Prayer for Judgment set forth in the Complaint.

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

ANSWER: Lupin denies that plaintiffs are entitled to the judgment and relief requested in paragraph D of the Prayer for Judgment set forth in the Complaint.

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

ANSWER: Lupin denies that plaintiffs are entitled to the judgment and relief requested in paragraph E of the Prayer for Judgment set forth in the Complaint.

AFFIRMATIVE AND SEPARATE DEFENSES AND COUNTERCLAIMS

Without prejudice to the denials set forth in its responses to paragraphs 1 through 30 of the Complaint, Lupin alleges the following Affirmative and Separate Defenses to the Complaint.

I. AFFIRMATIVE AND SEPARATE DEFENSES

First Affirmative and Separate Defense (Noninfringement of the '887 Patent)

31. Lupin's tramadol tablets (100 mg, 200 mg and 300 mg) that are the subject of ANDA No. 200503 do not and will not infringe any valid and enforceable claim of the '887 patent.

Second Affirmative and Separate Defense (Invalidity of the '887 Patent based on Title 35, U.S.C.)

32. The '887 patent, including at least 1-6, 13-20, 22-27 and 29-32 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

Third Affirmative and Separate Defense (Invalidity of the '887 Patent based on Obviousness-Type Double Patenting)

33. The '887 patent, including at least claims 1, 3, 13, 15, 16, 19, 23, 27, 29 and 31 thereof, is invalid under the doctrine of obviousness-type double patenting.

Fourth Affirmative and Separate Defense
(Noninfringement of the '430 Patent)

34. Lupin's tramadol tablets (100 mg, 200 mg and 300 mg) that are the subject of ANDA No. 200503 do not and will not infringe any valid and enforceable claim of the '430 patent.

Fifth Affirmative and Separate Defense
(Invalidity of the '430 Patent based on Title 35, U.S.C.)

35. The '430 patent, and each of claims 1 through 17 thereof, are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

Sixth Affirmative and Separate Defense
(Invalidity of the '430 Patent based on Obviousness-Type Double Patenting)

36. The '430 patent, and at least claims 1, 3, 5-7 and 11-13 thereof, are invalid under the doctrine of obviousness-type double patenting.

II. COUNTERCLAIMS

37. Defendants/Counterclaim-Plaintiffs Lupin Limited and Lupin Pharmaceuticals, Inc., (collectively, "Lupin"), bring the following Counterclaims against Plaintiffs/Counterclaim-Defendants Purdue Pharma Products, L.P., and Napp Pharmaceutical Group, Ltd., (collectively, "Purdue"), for a declaratory judgment that the '887 and '430 patents are invalid and/or not infringed by either Lupin or Lupin's tramadol tablets that are the subject of ANDA No. 200503.

The Parties

38. Counterclaim-Plaintiff Lupin Limited is a corporation organized and existing under the laws of India, and has a place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai, 400 051, India.

39. Counterclaim-Plaintiff Lupin Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the Commonwealth of Virginia, and has a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

40. Upon information and belief, Counterclaim-Defendant Purdue Pharma Products L.P. is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Upon information and belief, Purdue Pharma Products L.P. is an owner by assignment of the '887 and '430 patents.

41. Upon information and belief, Counterclaim-Defendant Napp Pharmaceutical Group Ltd. is a private limited company organized and existing under the laws of the United Kingdom, having a place of business at Cambridge Science Park, Milton Road, Cambridge, CB4 OGW. Upon information and belief, Napp Pharmaceutical Group Ltd. is an owner by assignment of the '887 and '430 patents.

Jurisdiction and Venue

42. This Court has subject matter jurisdiction over the counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a) and 1367, based on an actual controversy between Lupin and Counterclaim-Defendants Purdue Pharma Products L.P. and Napp Pharmaceutical Group Ltd. arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

43. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391, 1400(b), and by Counterclaim-Defendants' choice of forum.

First Counterclaim
(Declaration of Noninfringement of the '887 and '430 Patents)

44. Lupin hereby incorporates the allegations set forth in paragraphs 37-43 of the Counterclaims.

45. Counterclaim-Defendants Purdue Pharma Products L.P. and Napp Pharmaceutical Group Ltd. have filed a civil action in this Court against Lupin for allegedly infringing the '887 and '430 patents. There is an actual case or controversy between Lupin and Counterclaim-Defendants Purdue Pharma Products L.P. and Napp Pharmaceutical Group Ltd. concerning the alleged infringement of the '887 and '430 patents by Lupin and the Lupin Limited tramadol tablets that are the subject of Lupin Limited's ANDA No. 200503.

46. Neither Lupin, nor Lupin Limited's tramadol tablets that are the subject of ANDA No. 200503, infringe any valid and enforceable claim of the '887 patent.

47. Neither Lupin, nor Lupin Limited's tramadol tablets that are the subject of ANDA No. 200503, infringe any valid and enforceable claim of the '430 patent.

Second Counterclaim
(Declaration of Invalidity of the '887 and '430 Patents based on Title 35, U.S.C.)

48. Lupin hereby incorporates the allegations set forth in paragraphs 37-43 of the Counterclaims.

49. The '887 patent, including at least claims 1-6, 13-20, 22-27 and 29-32 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

50. The '430 patent, including claims 1 through 17 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

51. There is an actual case or controversy as to the validity of at least claims 1-6, 13-20, 22-27 and 29-32 of the '887 patent and claims 1 through 17 of the '430 patent.

Third Counterclaim
(Declaration of Invalidity of the '887 and '430 Patents for Obviousness-Type Double Patenting)

52. Lupin hereby incorporates the allegations set forth in paragraphs 37-43 of the Counterclaims.

53. The '887 patent, including at least claims 1, 3, 13, 15, 16, 19, 23, 27, 29 and 31, is invalid under the doctrine of obviousness-type double patenting.

54. The '430 patent, including at least claims 1, 3, 5-7 and 11-13, is invalid under the doctrine of obviousness-type double patenting.

55. There is an actual case or controversy as to the validity of at least claims 1, 3, 13, 15, 16, 19, 23, 27, 29 and 31 of the '887 patent and at least claims 1, 3, 5-7 and 11-13 of the '430 patent.

Prayer for Judgment

WHEREFORE, Lupin prays that this Court enter judgment against Purdue:

A. Declaring that the claims of the '887 and '430 patents are not and would not be infringed by Lupin;

B. Declaring that the claims of the '887 and '430 patents are invalid;

C. Declaring that the manufacture, use, sale, offer for sale, or importation of Lupin's tramadol tablets (100 mg, 200 mg, and 300 mg) that are the subject of ANDA No. 200503, would not, if marketed, infringe any valid claim of the '887 or '430 patents.

D. Determining that, under 35 U.S.C. § 285, this is an "exceptional case" and awarding Lupin its attorneys' fees in this action;

E. Awarding Lupin its costs and expenses incurred in this action; and

F. Awarding Lupin such other and further relief as the Court may deem proper.

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

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Dated: March 23, 2010

CERTIFICATE OF SERVICE

I, James L. Higgins, hereby certify that on March 23, 2010, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on March 23, 2010, I caused a copy of the foregoing document to be served on the above-listed counsel and on the following by e-mail:

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